

STATE OF MICHIGAN
DEPARTMENT OF LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE SERVICES
Before the Commissioner of Financial and Insurance Services

In the matter of

XXXXX

Petitioner

File No. 85738-001

v

Physicians Health Plan of Mid-Michigan
Respondent

_____ /

Issued and entered
this 26th day of November 2007
by Ken Ross
Acting Commissioner

ORDER

I

PROCEDURAL BACKGROUND

On October 12, 2007, XXXXX (Petitioner) filed a request for external review with the Commissioner of the Office of Financial and Insurance Services under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the material submitted, the Commissioner accepted the request on October 19, 2007.

The case required review by a medical professional. Therefore, the Commissioner assigned the matter to an independent review organization (IRO). On October 19, 2007, the IRO completed its review and sent its recommendations to the Office of Financial and Insurance Services.

II

FACTUAL BACKGROUND

The Petitioner is a member of Physicians Health Plan of Mid-Michigan (PHP). The PHP's certificate of coverage (the certificate) is the contract that defines his health care benefits.

The Petitioner has a history of acute left heel pain from chronic proximal plantar fasciitis. As an alternative to surgery, his podiatrist recommended extracorporeal shockwave therapy (ESWT), also called lithotripsy. When the podiatrist requested authorization for the shockwave therapy, PHP denied it.

The Petitioner appealed the denial. PHP conducted an internal review, but again denied the request. The Petitioner exhausted PHP's internal grievance process and received its final adverse determination letter dated August 22, 2007.

III ISSUE

Did PHP properly deny the Petitioner's request for authorization and coverage for extracorporeal shockwave therapy to treat plantar fasciitis?

IV ANALYSIS

Petitioner's Argument

The Petitioner has been diagnosed with chronic proximal plantar fasciitis. He suffers from acute pain in his left heel. He says that every step he takes is painful and makes him limp. He has tried many conservative treatments with little relief, including taping and padding, cortisone and other injections, night splints, multiple physical therapies, and orthotic castings. An examination of limb length and equality revealed he has a short leg so lifts were also incorporated. The Petitioner says that after all this treatment his heel pain did not decrease any further.

His podiatrist, XXXXX, recommended ESWT because conservative treatment had failed to relieve his symptoms. Since the Petitioner desired the least invasive procedure to prevent more lost time from work, he was advised that shockwave therapy was the best choice for him. Dr. XXXXX said "[the Petitioner] continues to exhibit significant antalgic gait and multiple treatments have failed to eliminate his symptomatology."

The Petitioner's primary care physician, XXXXX, DO, also supports his request for ESWT. In an undated letter Dr. XXXXX stated in part:

[The Petitioner] has been suffering with left heel pain for years from a bone spur. It compromises his ability to continue his daily activities including work. He has seen several podiatrists and has discussed his treatment options including surgery or ultrasound lithotripsy. I have recommended in favor of the lithotripsy and against the surgical procedure due to risks of scarring and worsening discomfort after surgery.

The Petitioner says that ESWT is a less invasive medically necessary treatment that will provide relief from his painful condition and allow him to perform his everyday functions without surgery. Therefore, he believes PHP should authorize and cover the ESWT.

PHP'S ARGUMENT

In its final adverse determination letter, PHP denied coverage for the ESWT, saying its effectiveness for the treatment of plantar fasciitis is considered to be unproven and therefore it is not a covered benefit. PHP's denial was based on provisions in Section 2 of the certificate, "What's Not Covered – Exclusions," which states in part:

E. Experimental, Investigational or Unproven Services

Experimental, Investigational and Unproven Services are excluded. The fact that an Experimental, Investigational, or Unproven Service, treatment, device or pharmacological regimen is the only available treatment for a particular condition will not result in Benefits if the procedure is considered to be Experimental, Investigational or Unproven in the treatment of that particular condition.

The term "unproven services" is defined in the glossary of the certificate:

Unproven Services – services that are not consistent with conclusions of prevailing medical research which demonstrate that the health service has a beneficial effect on health outcomes and that are not based on trials that meet either of the following designs.

- Well-conducted randomized controlled trials. (Two or more treatments are compared to each other, and the patient is not allowed to choose which treatment is received.)
- Well-conducted cohort studies. (Patients who receive study treatment are compared to a group of patients who receive

standard therapy. The comparison group must be nearly identical to the study treatment group.)

Decisions about whether to cover new technologies, procedures and treatments will be consistent with conclusions of prevailing medical research, based on well-conducted randomized trials or cohort studies, as described.

PHP used the Hayes Health Technology Brief to determine if prevailing medical research showed ESWT for plantar fasciitis was proven. According to PHP, the Hayes report concluded that: "optimal treatment parameters have not been established, patient selection criteria have not been adequately defined, and there is a lack of information regarding the durability of treatment effect or any long-term adverse effects of ESWT."

PHP believes its denial of coverage was correct.

IRO RECOMMENDATION

A practicing podiatrist, certified by the American Board of Podiatric Surgery, reviewed this case for the Commissioner. The IRO reviewer is a fellow of the American Society of Podiatric Dermatology, an associate of the American College of Foot Surgeons, and is published in the peer reviewed medical literature.

The IRO reviewer recommended upholding PHP's denial of coverage for shockwave therapy to treat plantar fasciitis. The IRO podiatrist stated there is some evidence that shockwave therapy could provide a moderate degree of relief in selected patients with chronic plantar fasciitis who have failed conventional treatment. However, there is a lack of information regarding the durability of this therapy and it is not known if there are long-term adverse effects. In addition, optimal treatment parameters and patient selection criteria have not been adequately defined.

The IRO reviewer further stated that there are conflicting results among the randomized controlled studies of shockwave therapy, and that a recent randomized, placebo-controlled, double-blinded clinical trial yielded results that contradicted positive results from previous studies.

Based on current literature, the IRO expert determined that ESWT is experimental or investigational for the treatment of chronic plantar fasciitis.

COMMISSIONER'S REVIEW

The Petitioner's certificate excludes coverage for unproven, experimental, and investigational services. The IRO reviewer concluded that ESWT is considered experimental or investigational for the treatment of plantar fasciitis, citing a number of studies and journal articles, including this excerpt from the Hayes report:

Conclusions: There is some evidence that ESWT can provide a moderate degree of pain relief in selected patients with chronic plantar fasciitis who have failed appropriate conservative therapy, with relatively few adverse effects. However, optimal treatment parameters have not been established, patient selection criteria have not been adequately defined, and there is a lack of information regarding the durability of treatment effect or any long-term adverse effects of ESWT. Therefore, a Hayes Rating of C is assigned to ESWT as an alternative to surgery in patients with chronic plantar fasciitis of at least a 6 month duration, who failed to respond to appropriate medical therapy.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner; in a decision to uphold or reverse an adverse determination the Commissioner must cite "the principal reason or reasons why the commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

Accordingly, the Commissioner accepts the conclusion of the IRO reviewer and finds PHP's final adverse determination is consistent with the certificate.

V ORDER

The Commissioner upholds PHP's August 22, 2007, final adverse determination. PHP is not responsible for covering extracorporeal shockwave therapy in this matter.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the Circuit Court for the county where the covered person resides or in the Circuit Court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Services, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.